Standard Operating Procedure – Study Set Up under the caBIG™ Program

This cover sheet controls the layout and components of the entire document.

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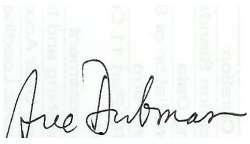
Department Approval:



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Note: This document will be issued for training on the Issue Date. The document will become available for use to trained personnel on the Effective Date. Before using this document, make sure it is the latest revision. Access the caBIG™ website to verify the current revision.

Revision History

Revision	Date	Author	Change Reference	Reason for Change
1.0	09/19/05	SOP Working Group	N/A	Initial release.

1. Purpose

This Standard Operating Procedure (SOP) describes the process for providing a consistent approach to setting up clinical research studies in a clinical data management application conducted under the caBIG™ Program.

2. Scope

This SOP applies to all clinical trial research studies covered under the caBIG™ Program and sponsored by the National Cancer Institute (NCI).

3. Requirements

3.1 The activities for setting up a clinical research study in the clinical data management application will begin when an approved protocol is submitted to the NCICB Study Designer.

3.2 The clinical study will be activated and released for production data entry after all study set-up activities are complete and:

- It is determined that Case Report Forms (CRFs) capture all requirements of the protocol.
- Edit checks are programmed and tested for accuracy, including data clarification messages, if applicable.
- Dictionaries are loaded on look-up tables for coding of adverse events, concomitant medications or other terms that may require coding.
- Batch load requirements and methods for loading external data have been identified (e.g., participant registration information, laboratory data).
- Test data entry of the CRFs are complete, including testing of derivations and validations specific to the protocol and data clarification messages for queries, if applicable.
- Data extracts are defined or selected and are appropriate for down-stream use.
- And, the clinical study set-up is approved for production release by the clinical protocol team.

4. References/Regulations/Guidelines

Section	SOP Number	Title
4.1	N/A	CDISC Glossary
4.2	CR-004	SOP for CDE Curation
4.3	AD-004	SOP for Information Security Compliance
4.4	AD-005	SOP for Protecting Patient Privacy
4.5	IT-001	SOP for Establishing User Accounts
4.6	IT-004	SOP for Electronic Loading of CDEs

5. Roles & Responsibilities

Role	Responsibility
Study Coordinator	• Author and maintain the plan for clinical data collected during the study in accordance with protocol specifications and/or requirements. • Coordinate 'test data entry' activities to verify the study has been set-up according to specifications and is ready for production. • Resolve and/or coordinate with clinical personnel, where appropriate, all coding issues or coding requirements for this study. • Coordinate for the timely loading of electronic data from external sources (*e.g.,* patient positions, site and investigator information from C3PR; laboratory data; other electronically submitted data for the conduct of the clinical trial). • Coordinate the selection or creation of extract data views or datasets for clinical trials personnel (*e.g.,* statistician for analysis; PI or clinical monitor personnel for data review; QC for audit activities).
Study Designer	• Coordinate load activities with the Study Coordinator and the NCICB Applications Support for loading of electronic data for the study (e.g., laboratory data, data from C3PR, electronic laboratory data). • Selects CDEs from the Application. • Set up the data entry screens in accordance with the protocol specifications. • Optimally reuse derivations and validations as well as data views and extracts already available in Application Standards Library domains to support the protocol requirements. • Coordinate testing activities of the study design (e.g., data entry, derivations and validations) with the Clinical Data Manager and Data Entry Test Personnel. • On an on-going basis, inform the Clinical Data Manager regarding updates to the standard validations, derivations and extract views that may be required. • Test all new or additional derivations, validations and extract views at the study level and appropriately submits for activation to the application's Standards Librarian. • Coordinate with the Study Coordinator and the IT Support Administrator the procedures for the loading of dictionaries for coding clinical trial data. • Create extracts for analytical tools or datasets from the clinical data management application to support statistical and clinical requirements for review and analysis. • Release the activated clinical study for data entry and batch load activities and communicates release to target audience.

Role	Responsibility
	• Communicate with the Application Standards Librarian on derivations or validations created for the specific study that need to be copied up to the Standards Library for future re-use.
Programmer	• Assist the Study Designer with the creation, testing and where appropriate, or the copying of derivations, validations and data extract views from the application standards library. • Provide input to the Study Designer for reviewing validations, derivations and extract views as required. • Complete and test all programs for pre-processing electronic data files in line with request and within set timeframes, including writing packages or functions to be called by the clinical data management application, where appropriate.
Data Entry Test Personnel	• Test data entry screens to verify cursor movement and that CRFs are the exact image of the paper CRF. • Communicate with Study Coordinator and Study Designer the testing data entry results for verification that derivations and validations execute appropriate.
NCICB Applications Support	• Review study access request in line with established standard practice. • Define the access rights in line with globally identified menu and study matrix access rights, allowing for variations at the specific study level as deemed necessary. • Periodically review all access rights to ensure they are in line with study requirements and global data management standards. • Ensure all access rights (other than “browse rights”) are removed once relevant data is frozen or locked, to ensure no further tampering of the data can occurs. • Ensure all access rights are removed for personnel no longer employed by the NCI or involved in execution of this particular protocol.
Application’s Standards Librarian	• Receive, review and manage requests for new metadata objects (CDEs), validations, derivations or data extract view constructs. • Receive and review new derivations, validations and data extract views created at a study level for copy to the standards library. • Update the appropriate standards library domain with the new or modified CDEs and activates them accordingly. • Coordinate with Study Designer to copy new derivations, validations or data extract formats to the application’s Standards Library for re-use. • Perform an on-going quality-control function to assure the standards library is aligned and consistent with the latest CDE updates or modifications.
	• Reviews the CRFs to assure that primary and secondary end-

Role	Responsibility
Study Statistician	points are collected and/or captured appropriately to satisfy analysis called for in the Stat Plan, where applicable. • Review the CRF construction to assure that data collection format and structure as well as extract formats will support safety and efficacy reporting requirements, where applicable.
Analytical Programmer	• Assists the Study Statistician in determining the programs required for reporting of the primary and secondary endpoints, and the ISS and ISE analyses and reporting requirements. • Write new analysis programs in line with specifications defined by the Study Statistician, where applicable. • Review and test extract files for reporting functionality. • Review and test analysis programs for functionality, utilizing identified test data. • Monitor the testing process throughout the data collection lifecycle. • Resolve any analysis program malfunctions to ensure optimal program performance. • Modify analysis programs in line with input from Study Statistician and in line with SOPs on programming. • Maintain program code for reports and listing as requested by the Study Statistician.

6. Attachments

This SOP will be used in conjunction with the attachments identified in the table below. These attachments must be used by all research sites conducting clinical trials under the caBIG™ Program and can be customized by individual research sites to accommodate format and content in accordance with local guidelines and/or requirements.

Title	Description
1) Procedure Description for Study Set-Up under the caBIG™ Program	This document provides instructions for setting up studies in the clinical data management application. It provides step-by-step guidance to assure that all studies are developed in a standard, quality manner.
2) Process Flow for Study Set Up	This document identifies the workflow activities, by role, for the steps identified in the Procedure for Study Set Up.